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| 10/689,270 | 10/20/2003 | David Ray Kraus | BHEAL-001 | 3733 |
| 67619 7590 04/18/2008 PAUL E. LEWKOWICZ, P.C. 3 DAVIS ROAD SOUTHBOROUGH, MA 01772-1824 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/689,270

Applicant(s)

KRAUS, DAVID RAY

Examiner

Maikhanh Nguyen

Art Unit

2176

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 8 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 9-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

1. This action is responsive to the Amendment filed 01/18/2008.

Claims 1-11 are pending in this application. Independent claims 1 and 10 have been amended. Claims 8 and 11 have been withdrawn. Claims 1, 10, and 11 are independent claims.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-7 and 9 remain rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 1 recites a system in the preamble only, the body of the claim merely contains software components. Thus, the recited invention is computer software per se, not tangibly embodied in a computer readable medium for causing the

computer to execute in a practical manner. Therefore, the claimed invention is directed to non-statutory subject matter.

Dependent claims 2-7 and 9 are rejected for fully incorporating the deficiencies of their base claim.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-7 and 9-10 remain rejected under 35 U.S.C. 102(a) as being anticipated by **Huyn et al.** (US 20020035486, publication date: 03/21/2002).

As to claim 1:

Huyn teaches a customized data collection system *(a computer-implemented questionnaire system and method for obtaining clinical data from subjects... questions ... are dynamically linked in dependence on previous responses received from the subject. The questions are organized into sets or forms*

containing logically related questions, and both the content of an individual form and the specific forms presented change as the subject provides responses) for individually tailoring computerized questionnaire administration (a computer-implemented questionnaire system and method for obtaining clinical data from subjects. .. questions ... are dynamically linked in dependence on previous responses received from the subject. The questions are organized into sets or forms containing logically related questions, and both the content of an individual form and the specific forms presented change as the subject provides responses) [see the Abstract; ¶¶ 0013-0018; see also, Figs.6-17 and the associated text], comprising computer instructions for:

- *a data collection interface to a plurality of user (e.g., a computer-assisted medical questionnaire for obtaining broad, longitudinal clinical data directly from subjects, also referred to as patients or users. The presented questions are selected dynamically as the subject responds to questions, and the conditions determining which questions are selected can themselves be updated without having to change the questionnaire software significantly. In contrast to standard computer-assisted questionnaires, which are rigid and preset, a questionnaire according to the present invention unfolds dynamically as the user responds to questions. Collected data are stored in a database that is structured to*

allow for subsequent data analysis and mining) [see ¶¶ 0037, 0067 and 0082; see also, Figs.10-13 and the associated text];

- a rules means to store and execute zero or more predetermined logic units; means to store and execute zero or more user defined logic units (see ¶¶ 0105, 0041, 0048, 0053, 0054, and 0055);
- a loading means to load the logic units in a prescribed order (see *Abstract*, ¶¶ 0013, 0015, 0053, 0061, 0070, 0074, and 0075), and
- a means to define and track the users, said user defined logic units, and each of relationship said user's hierarchical relationship to other said users (e.g., *the questionnaire design reflects the medical knowledge with which it is created, the path taken by a patient through the questions provides information about the patient's condition and medical history. Deeper-level questions, if presented, are associated with higher probabilities of particular diseases ... the number of questions that are triggered at each level by the question presentation logic is counted for each form, organ system, or symptom type ... Because the sequentially deeper levels of questions are designed to narrow in on specific positive signs or symptoms, answers to specific questions often can be correlated with specific conditions*" [see ¶¶ 038, 0074 and 0091-0095];

whereby the loading means first loads hierarchically superior user defined logic units before loading other user defined logic units, and ensures that superior user defined logic units are executed first; whereby the administration of the questions is altered based on said execution of said predetermined logic units and/or said user defined logic units, and whereby said questionnaire is customized in real time so that each said user can request the same questionnaire, but be administered, different sets of questions based on said user's answers (*e.g. Questions, forms, conditions and response items are represented as database objects. ... Questions and responses are stored as strings identified by question identifiers and response identifiers, respectively... The conditions shown represent two different types of logic that are evaluated at run time. At the highest level is form linking logic which determines which form to present next, i.e., the next set of potential questions. ...Question linking logic determines which of the potential questions in a given form will be presented to the subject... An additional optional relationship among questions is subservience, which is used to define the hierarchical level of questions (discussed further below). Representing questions and conditions as database objects provides increased flexibility and*

scalability of the system ... can edit these database objects without programming the system directly ... an additional level of conditional logic is employed intermediate between question linking and form linking logics ... Question assembly logic determines which potential questions to assemble into a form; assembled questions are referred to as included questions. Potential questions that are not assembled into a form will not be presented...For question linking logic the conditions refer to questions and responses in the current form, and the system re-evaluates the three conditions as response data are received for the current form ... If the user is authenticated, at state 118, the questionnaire options available to the specified user ID are provided to the web server from the database server and then transferred via the web server to the web browser. The user then selects the desired questionnaire (state 120), and at state 122, all eligible forms with associated form linking logic question linking logic and question assembly logic are sent from the database to the web server... If only the root form has been downloaded, then the web server automatically presents the root form. On subsequent iterations, the form is selected by evaluating one or more form linking conditions and selecting the form whose condition evaluates to true. The web server then dynamically assembles the questions by evaluating the

question assembly condition for each potential question in the form ... question linking condition for each included question, and any additional logical dependencies are downloaded to the web browser. The web browser evaluates all question linking conditions and displays the resulting questions to the user at state 130) [see ¶¶0053-0059, see also Figs.6-13 and associated text].

As to claim 2:

Huyn teaches an interface to add, modify, and delete logic units (a user-friendly interface... to add new forms, edit the names of existing forms, or delete forms ... can add edit, or delete questions ...allowing a researcher to change the questionnaire content as new information and correlations are discovered) [see ¶ 0067; see also Figs.6-13 and associated text].

As to claim 3:

Huyn teaches a testing means to analyze zero or more environmental variables, programmatic states, and stored data elements, available to the system to form a result; an execution means to trigger execution of said testing means before or after zero or more programmatic events; and a set of zero or more actions that will run in a prescribed order for each of said testing results (the evaluation conditions are based not only on responses to questions, but on other relevant

patient information stored in the database or in a different database in communication with the web server... a consistency test of the user's responses. Particularly if the user has entered positive responses to a number of screening questions, the same or similar questions are presented on different forms, and the responses are compared to verify their consistency ... If significant inconsistencies are found, the subject is alerted and asked to verify the correct response... inconsistencies are monitored and used to improve the question clarity) [see ¶¶ 0083-0084; see also Figs. 6-13 and associated text].

As to claim 4:

Huyn teaches the execution means control the programmatic action of the system including, among other things, branching to other said questionnaires (e.g., *The format of using branching logic and multiple levels of questions was designed in order to capture as much clinical information as possible*) [see ¶¶ 0055, 0074; see also Figs. 6-13 and associated text].

As to claim 5:

Huyn teaches alter means to modify the logic units, whereby the functionality of the logic units can be altered for a subset of the users (e.g., *The set of presented questions can change as the subject responds to questions, and thus a given subject may or may not see a particular form change in response to his or her*

answers or other data received) [see ¶ 0052; see also Figs. 6-13 and associated text].

As to claim 6:

Huyn teaches blocking means to lock one or more of said logic units from modification by other logic units (e.g., specify a new response or modify an existing response to a question on the current form ... adjusts the presentation to reflect the new response data) [see ¶¶ 0060, 0087; see also Figs. 6-13 and associated text].

As to claim 7:

Huyn teaches conditional means to lock only a subset of said other logic units from modifying a logic unit (e.g., *evaluating logic is preferably designed so that it can be modified or revised to reflect new medical knowledge or feedback from clinicians using the questionnaire system. For example, clinicians using the questionnaire may learn through experience that a certain response is being weighted too heavily and is actually not as meaningful as originally believed. This type of feedback concerning weighting can be provided by a clinician, or the evaluation logic can make this determination itself by analyzing the sensitivity, specificity, or error rate of the questionnaire or the feedback from the clinicians. If the evaluation logic determines that the weight accorded a response is inappropriate, it can register an alert or even adjust the weight automatically. In this way, feedback from clinicians and internal evaluations can be used both to*

validate and to monitor the performance of the questionnaire ... physicians can evaluate the question content and organization to ensure that relevant questions are being asked and that the questions are eliciting the intended response. As the content of the questionnaire system is updated, appropriate version control methods are applied so that it is always known which questions correspond to the stored response data) [see ¶ 0087; see also Figs. 6-13 and associated text].

As to claim 9:

Huyn teaches policing means to delete obsolete logic units that have been blocked from execution by previously loaded logic units (*e.g., the three different types of logic for selecting forms and questions ... determine which form should be presented next in such a situation ... In the case of question assembly logic, the three conditions refer to questions and responses in previous forms. For question linking logic, the conditions refer to questions and responses in the current form, and the system re-evaluates the three conditions as response data are received for the current form*) [see ¶¶ 0055-0056; see also Figs. 6-13 and associated text].

As to claim 10:

Note the rejection of claim 1 above. Claim 10 is the same as claim 1, except claim 10 is a computer-readable medium claim and claim 1 is a system claim.

Response to Arguments

4. Applicant's arguments filed 12/17/2007 have been fully considered but they are not persuasive.

a. **Regarding the 35 USC § 112 rejections:**

Applicant has amended claims 1, 2, 4, and 10 to overcome the 35 USC § 112 rejections. The prior 112 rejections are withdrawn.

b. **Regarding the 35 USC § 101 rejections:**

Applicant argues in substance that Claims 1-7 and 9 are statutory under 35 USC § 101.

The examiner disagrees.

Claims 1-7 and 9 recite a customized data collection system, which is interpreted as a computer program, however, the claim fails to assert the program recorded on an appropriate computer-readable medium so as to be structurally and functionally interrelated to the medium and permit the function of the descriptive material to be realized. Since a computer program is merely a set of instructions capable of being executed by a computer without a computer-readable medium needed to realize the

computer program's functionality, it is regarded as nonstatutory functional descriptive material.

c. Regarding the art rejections for claim 1:

Applicant argues that Huyn does not teach *"relationship means to define and track ... each of said user's hierarchical relationship to other said users."* [Remarks, pp. 9-10].

The examiner disagrees.

Huyn's teaching *"the questionnaire design reflects the medical knowledge with which it is created, the path taken by a patient through the questions provides information about the patient's condition and medical history. Deeper-level questions, if presented, are associated with higher probabilities of particular diseases ... the number of questions that are triggered at each level by the question presentation logic is counted for each form, organ system, or symptom type ... Because the sequentially deeper levels of questions are designed to narrow in on specific positive signs or symptoms, answers to specific questions often can be correlated with specific conditions"* [see ¶¶ 0074 and 0091-0095] covers *"relationship means to define and track ... each of said user's hierarchical relationship to other said users"*.

c. Regarding the art rejections for claims 6 and 7:

Applicant argues that Huyn does not teach “*blocking means to lock one or more of said logic units from modification by other logic units*” [Remarks, page 10].

The examiner disagrees.

Huyn's teaching “*evaluating logic is preferably designed so that it can be modified or revised to reflect new medical knowledge or feedback from clinicians using the questionnaire system. For example, clinicians using the questionnaire may learn through experience that a certain response is being weighted too heavily and is actually not as meaningful as originally believed. This type of feedback concerning weighting can be provided by a clinician, or the evaluation logic can make this determination itself by analyzing the sensitivity, specificity, or error rate of the questionnaire or the feedback from the clinicians. If the evaluation logic determines that the weight accorded a response is inappropriate, it can register an alert or even adjust the weight automatically. In this way, feedback from clinicians and internal evaluations can be used both to validate and to monitor the performance of the questionnaire ... physicians can evaluate the question content and organization to ensure that relevant questions are being asked and that the questions are eliciting the intended response. As the content of the questionnaire system is updated, appropriate version*

control methods are applied so that it is always known which questions correspond to the stored response data" [see ¶ 0087] is interpreted as read-on the claimed "blocking means to lock one or more of said logic units from modification by other logic units".

d. **Regarding the art rejections for claim 9:**

Applicant argues that Huyn fails to teach or suggest any "policing means to delete obsolete logic units that have been blocked from execution by previously loaded logic units." Though the cited portions of Huyn teach a means to "delete forms," this teaching is only described in the context of "questionnaire design" prior to administration [Remarks, page 10].

The examiner disagrees.

Huyn's teaching " *the three different types of logic for selecting forms and questions ... determine which form should be presented next in such a situation ... In the case of question assembly logic, the three conditions refer to questions and responses in previous forms. For question linking logic, the conditions refer to questions and responses in the current form, and the system re-evaluates the three conditions as response data are received for the current form) [see ¶¶ 0055-0056 & Figs. 6-13 and associated text]* covers "policing means to delete obsolete logic units that

have been blocked from execution by previously loaded logic units” as claimed.

Applicant is reminded that claimed subject matter, not the specification is the measure of the invention. Limitations in the specification cannot be read into the claims for the purpose of avoiding the prior art. See In re Self, 213 USPQ 1,5 (CCPA 1982); In re Priest, 199 USPQ 11, 15 (CCPA 1978).

Conclusion

5. The prior art made of record, listed on PTO 892 provided to Applicant is considered to have relevancy to the claimed invention. Applicant should review each identified reference carefully before responding to this office action to properly advance the case in light of the prior art.
6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed

within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact information

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maikhanh Nguyen whose telephone number is (571) 272-4093. The examiner can normally be reached on Monday - Friday from 9:00am – 5:30 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Hutton can be reached at (571) 272-4137.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published

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applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. N./

/Doug Hutton/
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